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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

FORMAN, B

ART UNIT

PAPER NUMBER

1655

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DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/269,573

Applicant(s)

HAYASHIZAKI, YOSHIHIDE

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 27-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☒ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

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DETAILED ACTION

1. This action is in response to papers filed 18 January 2000 in Paper No. 10 in which claims 1, 6, 8, 9, 13, 15, 16, 18, 21-25, & 27-30 were amended and claim 26 was canceled and claim 31 was added. All of the amendments have been thoroughly reviewed and entered. All of the arguments have been thoroughly reviewed are discussed below. The previous rejections under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments. The previous rejections of Claims 23-25 under 35 U.S.C. 102(e) and under 35 U.S.C. 103(a) are withdrawn in view of the amendments.
2. Currently claims 1-25 & 27-31 are under prosecution. New grounds for rejection are discussed.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
4. The previous rejection of Claims 1-8 & 19-22 & 27-30 under 35 U.S.C. 103(a) as being unpatentable over Gifford (U.S. Patent No. 5,750,335, filed 22 April 1993) in view of Chirikjian et al. (U.S. Patent No. 5,763,178, filed 7 June 1996) and Chee et al. (U.S. Patent No. 5,837,832, filed 16 May 1995) in the Office Action filed 19 October 1999 in Paper No. 7 is maintained. The text of the previous rejection, not included in this action, can be found in the above referenced action in paragraph 6.

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Response to Arguments

5. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections. Applicant argues that the recited teachings would not direct one of ordinary skill to use "use longer sequences" as probes and in particular, applicant argues that Chee teaches away from using long and specific sequences. This argument is not found persuasive because, as Applicant acknowledges, Chee et al. teach that probes may be "very long" and in particular they teach the claimed probes having **part of** a sequence of full-length gene (Column 7, lines 2-5 and 55-57). Applicant further argues that the cDNA of Gifford is the test nucleic acid not the claimed reference nucleic acid. However, the cited reference, with careful review, reveals that the test and the reference nucleic acid is cDNA (Column 4, lines 51-51).

6. The previous rejection of Claims 9-18 under 35 U.S.C. 103(a) as being unpatentable over Chirikjian et al. (U.S. Patent No. 5,763,178, filed 7 June 1996) in view of Chee et al. (U.S. Patent No. 5,837,832, filed 16 May 1995) and Goldrick (U.S. Patent No. 5,891,629, filed 28 September 1995) in the Office Action filed 19 October 1999 in Paper No. 7 is maintained. The text of the previous rejection, not included in this action, can be found in the above referenced action in paragraph 7.

Response to Arguments

7. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation is clearly recited in the above referenced rejection. Applicant also argues that the references do not disclose or suggest part or all of a full-length sequence as a probe. This argument is not found persuasive, see paragraph 5, above.

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8. The previous rejection of Claims 28-30 under 35 U.S.C. 103(a) as being unpatentable over Chee et al. (U.S. Patent No. 5,837,832, filed 16 May 1995) in view of Chirikjian et al. (U.S. Patent No. 5,763,178, filed 7 June 1996) in the Office Action filed 19 October 1999 in Paper No. 7 is maintained. The text of the previous rejection, not included in this action, can be found in the above reference action in paragraph 8.

Response to Arguments

9. Applicant argues that the references do not disclose or suggest part or all of a full-length sequence as a probe. This argument is not found persuasive, see paragraph 5, above.

New Grounds for rejections necessitated by amendment

8. Claim 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford (U.S. Patent No. 5,750,335, filed 22 April 1993) in view of Zoltukhin et al. (U.S. Patent No. 5,874,304, filed 18 January 1996) and Fleck et al. (Nucleic Acids Research, 1994, 22(24): 5289-5295).

Regarding Claim 23, Gifford teaches a substance specifically bindable to a mismatched base pair wherein said substance is labeled (Column 5, lines 13-17). Gifford does not teach the label is GFP. However, GFP labeled proteins were known in the art at the time the claimed invention was made as taught by Zoltukhin et al. who teaches the advantages of GFP i.e. it does not require cofactors or substrates and it is small in size (Column 1, lines 52-59 and Column 8, lines 22-27). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Gifford with the teachings of Zoltukhin et al. to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to apply the GFP

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label of Zoltukhin et al. to the labeled mismatched base pair binding substance of Gifford for the advantages of GFP taught by Zoltukhin et al.

Regarding Claim 24, Gifford teaches a substance specifically bindable to a mismatched base pair wherein said substance is labeled (Column 5, lines 13-17) wherein the substance is a mismatch binding protein "such as MutS protein" (Column 7, lines 14-25), but Gifford does not teach the mismatch binding protein binds a c/c mismatch. However, c/c mismatch binding proteins were well known in the art at the time the claimed invention was made as taught by Fleck et al. who teach the MutS homologue of *Schizosaccharomyces pombe*, *swi4* which specifically binds to c/c mismatched base pairs (page 5292). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Gifford with the teachings of Fleck et al. and Zoltukhin et al. to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to modify mismatch binding substance of Gifford with the mutS homologue of Fleck et al. for the expected benefit of base-specific mismatch binding as taught by Fleck et al. (page 5294, last paragraph).

Regarding Claim 25, Gifford teaches a substance specifically bindable to a mismatched base pair wherein said substance is labeled (Column 5, lines 13-17) wherein the substance is a mismatch binding protein "such as MutS protein" (Column 7, lines 14-25), but Gifford does not teach the substance is a c/c mismatch binding protein. However, c/c mismatch binding proteins were well known in the art at the time the claimed invention was made as taught by Fleck et al. who teach the MutS homologue of *Schizosaccharomyces pombe*, *swi4* which specifically binds to c/c mismatched base pairs (page 5292). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Gifford with the teachings of Fleck et al. to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to modify mismatch binding substance of Gifford with the mutS homologue of Fleck et

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al. for the expected benefit of base-specific mismatch binding as taught by Fleck et al. (page 5294, last paragraph).

9. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chee et al. (U.S. Patent No. 5,837,832, filed 16 May 1995) in view of Chirikjian et al. (U.S. Patent No. 5,763,178, filed 7 June 1996) as applied to claim 28 above and further in view of Gifford (U.S. Patent No. 5,750,335, filed 22 April 1993). Chee et al. teach a substrate having a surface on which one or more nucleic acid fragments having part of a full-length gene are fixed in a hybridizable condition (Column 7, line 55-Column 8, line 11). Chee et al. do not teach the nucleic acid is cDNA. However, cDNA was known and routinely practiced in the art at the time the claimed invention was made as taught by Gifford et al. who teaches that a substrate having a surface on which nucleic acids are fixed in a hybridizable condition (Column 5, lines 1-6) wherein the nucleic acid is cDNA (Column 4, lines 50-51). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the article of Chee et al. with the teachings of Gifford to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to modify the nucleic acid fragments of Chee et al. with the cDNA of Gifford for the obvious benefit of hybridizing to mRNAs.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.

July 6, 2000

